FDA 510(k) Premarket Notification

K183687 LifeWindow LW8 Lite

CLEARED

Sep 25, 2019
271 days to decision

K183687 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k183687/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 28, 2018
Decision date	Sep 25, 2019
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Digicare Biomedical Technology, Inc.**
Location	Boynton Beach, FL, US
Contact	Eduardo Miranda
510(k) history	1 submissions · 1 cleared · 2019-2019